# The Effect of Natural Raw Meal on Diabetic and Hypercholesterolemic Patients

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## ABSTRACT

**Objective:** This study was designed to determine the effect of Natural Raw Meal (natural raw food, provided by Erom company, non-co Natural Raw Meal ked include grains, vegetables, fruits, mushrooms, sea plants and some functional materials. ) to improve lipid and glucose plasma in hypercholesterolemic and diabetic patients.

**Methods:** This is an experimental study designed for 6 weeks, with 42 participants (25 subjects for the cholesterol groups and 22 subjects for the diabetic groups, while 5 participants suffer from both diabetes and hypercholesterolemia recruited in this study. Before the study all participants will be check for lipid profiles for the hypercholesterol groups and glucose profiles for the diabetes groups. At the end of the study all participants has to rechecked their laboratorium status.

**Results:** The results of the hypercholesterol groups, is that total cholesterol after consuming Natural Raw Meal for six weeks, decrease significantly from 250.16 ± 24.37 mg/dl (baseline) to 229.80 ± 25.35 mg/dl (after study). LDL decrease significantly after the study, from 177.92 ± 24.27 mg/dL (baseline) to 159.92 ± 28.54 mg/dL (after study). HDL is also decreassing. Triglyceride is slightly increase after the study but not significant. Glucose levels and HbA1C in the diabetic groups, after the study tend to

decrease, fasting glucose decreased significantly from 208.14 ± 73.84 to 177.64 ± 63.49 and 2 hours post prandial glucose decreased from 298.36 ± 16.64 to 239.59 ± 95.30. HbA1C also decreased but not significant from 10.15 ± 2.20 % to 9.60 ± 1.62 %. All subjects in cholesterol and diabetic patients was no different in BMI before and after experiment and also there are no different in total calorie intake before and after experiment.

**Conclusions:** Natural Raw Meal can improve lipid profil and blood glucose plasma in the hypercholesterolemic and diabetic patients. HbA1C tends to decrease but not significant yet, maybe this parameter need a longer study.

## INTRODUCTION

Diabetes is a chronic metabolic disease characterized by hyperglycemia affecting carbohydrate or sugar utilization due to inadequate production of insulin by the pancreatic islets of Langerhans (type I diabetes) or insulin resistant condition with inadequate insulin secretion (type II diabetes). According to WHO report, the number of the adult population affected by type II diabetes was about 135 million worldwide in 1995 and estimated to be 300 millions by 2025 (Kim et al).

Complications from diabetes such as retinopathy, nephropathy, neuropathy, and vasculopathy are the major causes of morbidity and mortality in people with diabetes. Since each complication has been linked to hyperglycemia, aggressive controlling of serum glucose level has been the mainstay of treatment (Kim et al).

Diabetes is also a key factor in the predictive equations for CVD. It is therefore appropriate that dietary advice determined to be of use in the prevention and treatment of CVD should be considered as part of the advice for the prevention and treatment of diabetes. Thus, although an attempt will be made to discuss the effects of plant foods on glycemia, a large part of this discussion of the diabetic diet will deal with the role of plant foods in prevention of the major complications of diabetes, especially CVD (Jenkins et al, 2003).

In type 2 diabetes, in addition to a focus on caloric content of carbohydrate, consideration continues to be given to the role of the glycemic index as a determinant of postprandial hyperglycemia and overall metabolic control. Nevertheless, consensus recommendations do not support widespread use of the glycemic index. An area of some change is a more clear endorsement of including monounsaturated fatty acids.

Current recommendations are that monounsaturated fatty acids and carbohydrates combined should provide 60–70% of daily energy intake, with individual flexibility in the respective proportions, whereas intake of saturated fats is limited to < 10% of energy intake. This new emphasis reflects greater awareness of the importance of responding to individual and cultural dietary preferences and the need to address treatment of both hyperglycemia and dyslipidemia in diabetes mellitus (Kelley, 2003).

One additional issue is related to fiber intake. Current recommendations for the general population are that men have a fiber intake of ≈38 g/d and women have ≥25 g/d. There has been specific interest in the role that dietary fiber may have in the nutritional management of DM. Benefits of fiber were found with regard to glycemic control, HDL and LDL cholesterol, and triacylglycerols (Kelley, 2003).

Coronary artery disease is also major cause of death in in most developed countries, and blood cholesterol is a major risk factor. Dietary and pharmacologic reductions in total and LDL cholesterol decrease the risk of coronary events, and dietary intervention is the first-line approach. Increasing dietary fiber has been recommended as a safe and practical approach for cholesterol reduction (Brown et al, 1999).

Plasma concentrations of LDL are influenced by both genetic and environmental factors. Although it is difficult to alter genetic factors, modifiable environmental factors such as smoking or dietary patterns could be targeted in preventive interventions aimed at lowering LDL (Djosse et al, 2004)

The mechanism by which fiber lowers blood cholesterol remains undefined. Evidence suggests that some soluble fibers bind bile acids or cholesterol during the intraluminal formation of micelles. The resulting reduction in the cholesterol content of liver cells leads to an up-regulation of the LDL receptors and thus increased clearance of LDL cholesterol. However, increased bile acid excretion may not be sufficient to account for the observed cholesterol reduction (Brown et al, 1999).

Other possibilities that undigested carbohydrate that reaches the colon is fermented by intestinal microflora to short-chain fatty acids and gases. Short chain fatty acids include acetate, butyrate, and propionate; butyrate is a preferred fuel for the cells of the colonic mucosa. Shortchain fatty acid production has been related to lowered serum cholesterol and decreased risk of cancer. Undigested carbohydrates increase fecal wet weight and dry weight and speed intestinal transit (Slavin et al, 1999).

Increased intake of fruits and vegetables has been endorsed as public health policy for a number of reasons. Displacement of saturated fat and increased intake of fiber have been seen as general reasons for increasing fruit and vegetable consumption (Jenkins et al, 2003).

Nutraceuticals and functional foods have become an interest worldwide and their ability to prevent or mitigate chronic diseases such as diabetes, cardiovascular disease, and cancer is being explored (Kim et al). The increasing number of raw nutraceuticals food has attract many attention lately.

Nutraceutical raw foods contains whole grain which are important sources of dietary fiber, resistant starch, oligosaccarides, trace minerals, vitamins, and other compounds of interest in disease prevention including phytoestrogens and antioxidants, has many functional benefit in increasing health (Kim et al).

The healthy diet has been proven to lower cholesterol and glucose in diabetic and hypercholesterolemic patients. But still, there is a controversy about the composition of food, and the amount of fiber that can reduce both cholesterol and glucose levels. Natural Raw Meal product (composition of Natural Raw Meal can be seen in Table 1) is believed to be suitable for diabetic and hypercholesterolemic patients, for this reason we conduct this study in Indonesia.

**Table 1. Composition of Natural Raw Meal**

| | |
|---|---|
| Grains | brown rice, alpha-brown rice, glutinous millet, Indian millet, millet, job's tear, glutinous brown rice, barley, red bean, agaricus rice, hongkuk barley, black sesame |
| Vegetables | kale, angelica utilis, cabbage, dropwort, radish leaves, broccoli, leek, barley leaf powder, potato |
| Pulses | soybean powder, small black bean |
| Bulbs | carrot, burdock, radish, codonopsis lanceolata |
| Fruits | pumpkin, citron, tomato |
| Mushrooms | shiitake mushroom, reishi mushroom |
| Marine plants | laver, brown seaweed, tangle, sea lettuce |
| Wild plants | pine needle |

## SUBJECTS AND METHODS

### MATERIAL

Natural Raw Meal is provided by EROM company. The composition of Natural Raw Meal can be seen in Table 1.

### SUBJECT

Participants are people from local areas including those attending the church, clinic, and local social activities. Participants are recruited in seminars held in clinic that explaining what Natural Raw Meal is and its function to our health. Those who meet the inclusion criteria and would like to participate should sign the informed consent before the study.

Individuals are eligible for this study if their age ≤ 65 years old, have history of diabetes (meeting the criteria of fasting plasma glucose > 126 mg/dl or serum glycated hemoglobin (HbA1C) > 6,5 % for the diabetes group, and total cholesterol > 200 mg/dL for the hypercholesterolemic groups. Individuals are excluded from this study if they have serious medical complications such heart disease, stroke, or taking medical drug for hypercholesterolemia

After completing the informed consent, participants are screened for lipid and glucose profile. A total of 42 patients (25 patients for the cholesterol group and 22 patients for the diabetes group, while 5 patients suffer both diabetic and hypercholesterolemic) are recruited in this study. This study takes place in Mutiara Gading Health Clinic Kelapa Gading, Jakarta.

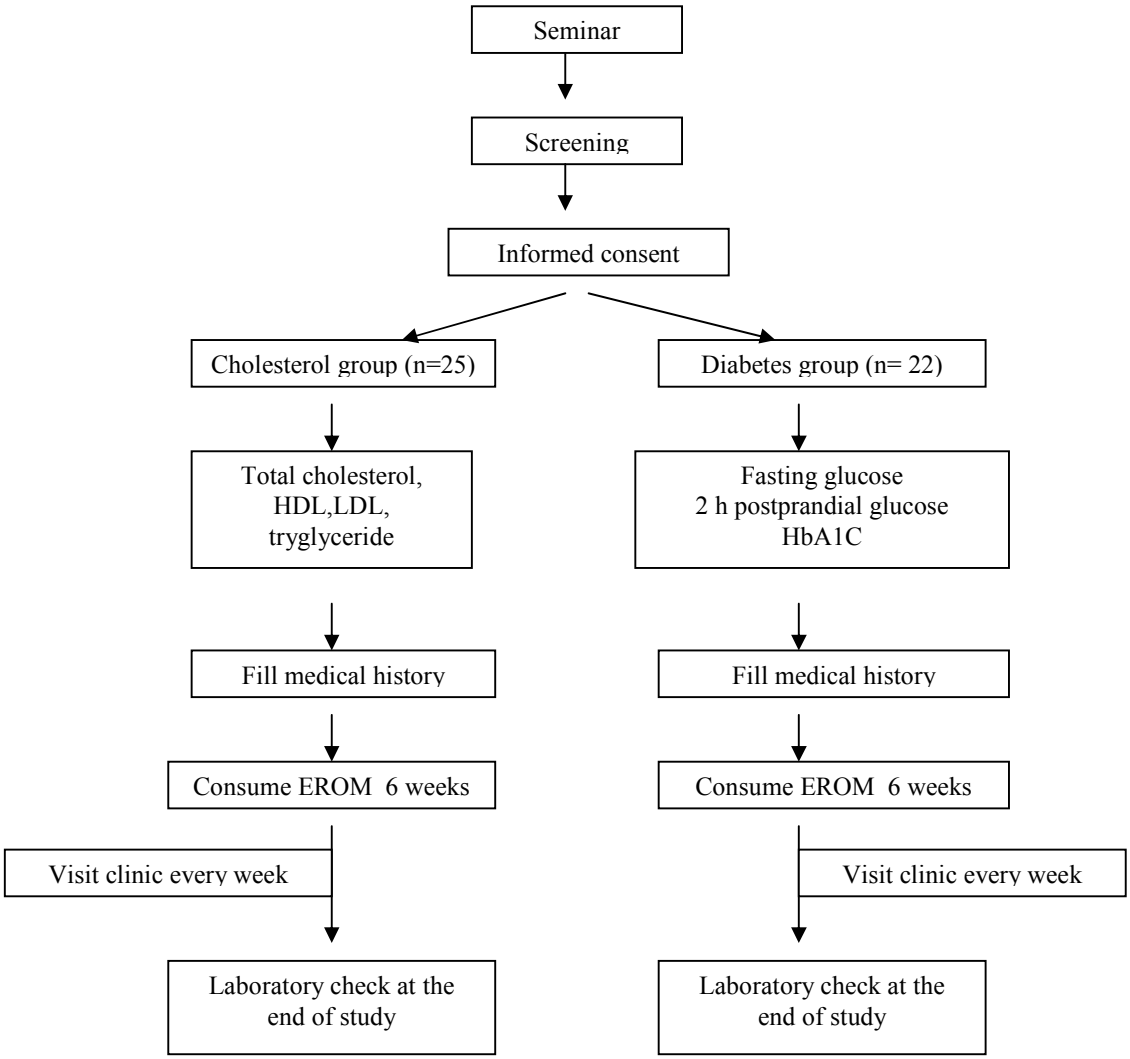
**METHODS**

This is a study of pre and post experimental design. Before the study, all subjects will be asked to fill in 3 days food recalls and their medical histories background. Subjects from diabetes group will be checked for fasting glucose, 2 hours postprandial glucose, and HbA1C. As for subjects in the hypercholesterolemic will be checked for total cholesterol, HDL, LDL, and tryglyseride.

Every subject will consume 2 sachets of Natural Raw Meal daily, in the morning and in the evening. Every subject are encouraged to replace their breakfast and dinner

with Natural Raw Meal, and told to drink lots of water while consuming Natural Raw Meal.

Everyday all the subjects will be monitored by phone from the clinic. All complaints and improvement reactions were noted. Once a week, all the subjects must gathered in clinic, and will be checked by a physicians. After 6 weeks, all the subjects must rechecked their laboratorium analysis.



## RESULTS

Characteristics of participants are shown in table 2.

**Table.2. Characteristic of all subjects**

| | |
|---|---|
| Cholesterol groups | 25 subjects |
| Diabetes groups | 22 subjects |
| Subjects suffers both diabetes & hypercholesterolemia | 5 subjects |
| Mean age (years) | 52.41 ± 9.33 |
| BMI ($kg/m^2$) | 26.87 ± 4.12 |
| Men : women | 20 men : 22 women |

Total participants in this study are 42 subjects, 25 subjects in the cholesterol groups and 22 subjects in the diabetes groups, while 5 subjects suffers both diabetes as well as hypercholesterolemia . Mean age participants is 52.41 ± 9.33 years, and BMI of participants are 26.87 ± 4.12 $kg/m^2$.

**Table 3. Basic characteristic of the subjects in the cholesterol group (n=25)**

| | |
|---|---|
| Mean age (years) | 50.56 ± 11.96 |
| BMI (kg/m$^2$) | 25.71 ± 3.98 |
| Total calorie intake/day (cal/day) | 2024.56 ± 469.35 |
| Mean sistolic pressure (mg/dL) | 136.40 ± 23.47 |
| Mean diastolic pressure (mg/dL) | 92.20 ± 14.22 |

Total participants in the cholesterol group is 25 subjects, with mean BMI 25.71 ± 3.98 kg/m$^2$. Mean sistolic and diastolic pressure are 136.40 ± 23.47 mm Hg and 92.20 ± 14.22 mm Hg. Mean total calorie intake are 2024.56 ± 469.35 cal/day.

**Table 4. Characteristic of the diabetic subjects (n=22)**

| | |
|---|---|
| Mean age (years) | 53.27 ± 6.14 |
| BMI (kg/m$^2$) | 26.87 ± 4.12 |
| Total calorie intake/day (cal/day) | 2073.41 ± 303.82 |
| Mean sistolic pressure (mg/dL) | 139.77 ± 21.18 |
| Mean diastolic pressure (mg/dL) | 94.77 ± 13.84 |

P < 0.05 : significant

Total participants in the diabetes group is 22 subjects, with mean BMI 26.87 ± 4.12 kg/$m^2$. Mean sistolic and diastolic pressure are 139.77 ± 21.18 mm Hg and 94.77 ± 13.84 mm Hg. Mean total calorie intake are 2073.41 ± 303.82 cal/day.

**Table 5. Results of subjects in cholesterol group (n=25)**

| **Components** | **Before study** | **After 6 weeks of study** | **p value (significancy)** |
|---|---|---|---|
| Total cholesterol (mg/dL) | 250.16 ± 24.37 | 229.80 ± 25.35 | 0.001 |
| LDL (mg/dL) | 177.92 ± 24.27 | 159.92 ± 28.54 | 0.003 |
| HDL (mg/dL) | 53.40 ± 9.87 | 48.52 ± 9.33 | 0.14 |
| Tryglyceride (mg/dL) | 168.20 ± 67.43 | 179.32 ± 100.56 | 0.491 |

P < 0.05 : significant

The results of the hypercholesterolemia are shown in table 5. As shown in table 5, total cholesterol after consuming Natural Raw Meal for six weeks, decrease significantly from 250.16 ± 24.37 mg/dl (baseline) to 229.80 ± 25.35 mg/dl (after study).

LDL as one of major risk for heart disease, also decrease significantly after study, from 177.92 ± 24.27 mg/dL (baseline) to 159.92 ± 28.54 mg/dL (after study).

Unfortunately HDL, which is a good cholesterol is also decrease. The possible mechanism for this might be inadequate physical activity or less exercise because almost all the participants in the cholesterol groups are elderly (mean age subjects in the cholesterol group 50.56 ± 11.96 years). Triglyceride is also slightly increase after the study but not significant.

**Table 6. Results of subjects in the diabetes group (n=22)**

| **Components** | **Before study** | **After 6 weeks of Study** | **p value (significancy)** |
|---|---|---|---|
| Fasting glucose (mg/dl) | 208.14 ± 73.84 | 177.64 ± 63.49 | 0.019 |
| 2h postprandial (mg/dl) | 298.36 ± 16.64 | 239.59 ± 95.30 | 0.025 |
| HbA1C(%) | 10.15 ± 2.20 | 9.60 ± 1.62 | 0.123 |

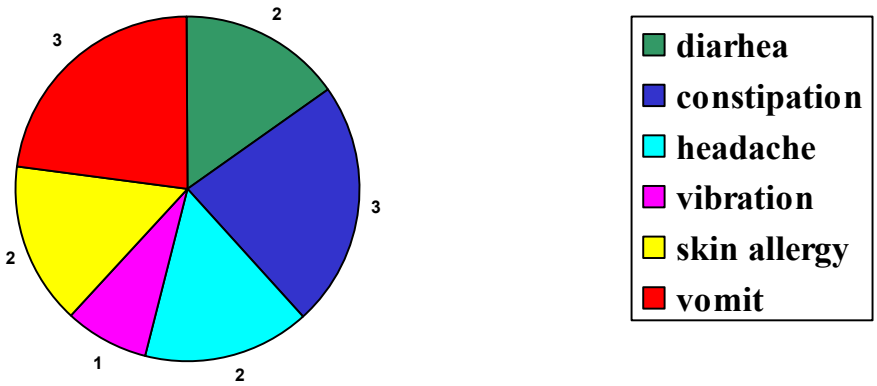
$P < 0.05$ : significant

Changes glucose levels and HbA1C of the subjects before and after study are summarized in table 5. All the components tends to decrease, fasting glucose decrease significantly from 208.14 ± 73.84 mg/dL to 177.64 ± 63.49 mg/dL and 2 hours post prandial glucose decrease from 298.36 ± 16.64 mg/dL to 239.59 ± 95.30 mg/dL. HbA1C is also decrease but not significant from 10.15 ± 2.20 % to 9.60 ± 1.62 %.

**Improvement reactions**

Nearly 10 participants dropped out from this study, and most of their complaints are abdominal discomfort and headache. Summary of improvement reactions are shown in Figure 1.

**Figure 1. Improvement reactions through drop out participants**




Improvements reactions through drop out participants, most of the complaints are diarrhea (3 participants), vomitting (3 participants), and constipations (3 participants), while other reactions are headache, vibration

**Table 7. Improvement reactions of all subjects**

| Symptoms | Number of subjects (people) |
|---|---|
| Constipation | 9 |
| Headache | 9 |
| Often feel hungry | 3 |
| Abdominal discomfort | 1 |
| Flattus | 3 |
| Full stomach | 7 |
| Foot edema | 1 |
| Erectile disfunction | 1 |
| Itching | 3 |
| Drowsiness | 2 |
| Chest discomfort | 1 |
| Dyspnea | 1 |
| Nausea | 1 |
| Diarrhea | 1 |
| Cramps | 1 |
| Heart vibration | 1 |

From table 7, major improvements reactions off all participants are constipations and headache ( 9 participants).

**Discussion**

The Cholesterol group patients in this experimental study are 25 people. All subject are no different in BMI before and after experiment, also there are no different in total calorie intake before and after experiment during 6 weeks of the study.There are just slightly lower calorie intake from the beginning to the end of the study. This indicated that although they only take Natural Raw Meal in the morning as well as at the evening which consist of only 150 kcal/sachet, but they take other meals instead. For reducing hypercholesterolemia patients, should take less cholesterol from the diet or take more fiber and flavonoids which known to have an effect of lowering cholesterol (Guthrie and Kurowska, 2001).

This conditions are the same as the 22 patients in diabetic groups. There are no different in BMI and total calorie intake, but just the ttal calorie intake is slightly lower from the beginning to the end of study. The food habit are no different from cholesterol and diabetic patients. For diabetic patients, the HbA1C are not significantly different but just slightly lower from the beginning. This maybe cause by the food habit of the diabetic patients. That's need more longer study to lower the HbA1C to see the effect of Natural Raw Meal . If all the patients did following the meal plan with discipline, maybe the

result will be better. Especially in diabetic patients, Natural Raw Meal can cause cell more better to metabolized glucose, so the level of glucose can significantly decreased.

For hypercholesterolemic patients the experiment has a good result. There is a significant effect of lower total cholesterol and LDL. Maybe this is because the content of the flavonoids and fiber in Natural Raw Meal. The result of this study is in connection with other study in animals and cell culture studies (Guthrie and Kurowska, 2001).

Blood glucose level of diabetic patients were decreased for fasting and postprandial time significantly. Since the main material of Natural Raw Meal include grains and vegetables, Natural Raw Meal might have a positively effect on glucose whether fasting as well as 2 hour postprandial blood glucose (Kim et al)

The composition of Natural Raw Meal has positive effect on lowering blood glucose and cholesterol. As we know the composition of Natural Raw Meal are grains, vegetable, and fruits, which have low glycemic index. Other composition that we don't really know, might also have some positive effects on glucose and cholesterol. The advantages of Natural Raw Meal, it consist of diverse grains, vegetables and fruits can be consumed even with taking just one sachet Natural Raw Meal. As we know nutraceuticals and functional foods has been increasingly worldwide due to their ability to influence metabolic and prevent chronic diseases including hypercholesterolemia and diabetes ( Kim et al).

## CONCLUSIONS

From the result of the study, Natural Raw Meal product is effective in improving lipid profile of the hypercholesterolemic patients by consuming Natural Raw Meal for 6 weeks. Total cholesterol, LDL decreased significantly at the end of study, but HDL is also decreased due to the possibility of lack of activities.

Natural Raw Meal products is also effective in reducing fasting glucose and 2 hours postprandial for the diabetic groups at the end of study. HbA1C is also decrease at the end of study, though not significant, longer study is needed to confirm the effectiveness of Natural Raw Meal in improving HbA1C in the diabetic patients.

**Reference**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